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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,422	06/25/2002	Michael Cawthorne	0380-P02754USO	3305

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EXAMINER	
DEJONG, ERIC S	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,422	CAWTHORNE ET AL.	
	Examiner	Art Unit	
	Eric S. DeJong	1631	

-- The MAILING DATE of this c mmunication appears on the cover sheet with the correspondence address --

Period for R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34 and 38-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *1-34 and 38-53* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendment containing amendments to the claims, filed on 30 November 2001, is acknowledged and replaces all previous versions of the claims in the instant application. Amendments to claims 4, 5, 7, 8, 10, 12, 14, 16-18, 22-27, 29, 32, 33, 38, 41-44 and 52, cancellation of claims 35-37, and the addition of claim 53 are acknowledged. Claims 1-34 and 38-53 are pending in the instant application.

Lack of Unity

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-33, 52 and 53, drawn to a method of screening for an agent to determine its usefulness in treating insulin resistance. If this group is elected then the below summarized sequence election is also required.

Group II, claim 38, drawn to a method of treating a condition characterized by insulin resistance in a patient. If this group is elected then the below summarized sequence election is also required.

Group III, claim(s) 39-44, drawn to a method of determining the nature of degree of insulin resistance in a sample of relevant tissue from a human or animal subject.

Group IV, claim(s) 34 and 45-51, drawn to a protein which is differentially expressed in relevant tissue from or representative of subjects having differential levels of insulin sensitivity and which is obtainable by the method of two-dimensional gel electrophoresis carried out on said tissue or a protein-containing extract thereof. If this group is elected then the below summarized sequence election is also required.

The inventions listed as Groups I-IV do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature between the inventions of Groups I-IV is the identification of insulin sensitivity related to the expression of certain proteins in insulin sensitive subjects and is already well known in the art. For example, Taylor et al. teaches a method of treating non-insulin dependent diabetes mellitus in a human subject by administration of a pancreatic polypeptide. Further, Tayler et al. asserts that an identified increase in insulin sensitivity in said subjects is appropriately addressed by said treatment and avoids potential health complications. See Taylor et al., column 1, lines 10-21 and 43-54. Therefore, the special technical feature linking the inventions of Groups I-IV does not constitute a special technical feature as defined by PCT Rule 13.2, as is does not define a contribution over the prior art.

The special technical feature of Group I is considered to be a method of screening for an agent to determine its usefulness in treating insulin resistance, the method comprising establishing a paradigm in which at least one protein is differentially

expressed in relevant tissue in relevant tissue from, or representative of, subjects having differentially levels of insulin sensitivity, obtaining a sample of relevant tissue taken from, or representative of, and insulin resistant subject, which has been treated with the agent being screened, determining the presence, absence or degree of expression of the differentially expressed protein or proteins in the tissue from, or representative of, the treated subject, and selecting or rejecting the agent according to the extent to which it changes the expression, activity or amount of the differentially expressed protein or proteins in the treated insulin resistant subject.

The special technical feature of Group II is considered to be a method of treating a condition characterized by insulin resistance in a patient, the method comprising administering a therapeutically or prophylactically effective amount of such an agent.

The special technical feature of Group III is considered to be a method of determining the nature or degree of insulin resistance in a sample of relevant tissue from a human or animal subject which comprises establishing a paradigm in which at least one protein is differentially expressed in relevant tissue from or representative of subjects having differential levels of insulin sensitivity, obtaining a sample of the tissue and determining the presence, absence or degree of expression of the differentially expressed protein or proteins in the sample and relating the determination to the nature or degree of insulin resistance to a previous correlation between such a determination and clinical information.

The special technical feature of Group IV is considered to be a protein which is differentially expressed in relevant tissue from or representative of subjects having

or degree of insulin resistance to a previous correlation between such a determination and clinical information.

The special technical feature of Group IV is considered to be a protein which is differentially expressed in relevant tissue from or representative of subjects having differential levels of insulin sensitivity and which is obtainable by the method of two-dimensional gel electrophoresis carried out on said tissue or a protein containing extract thereof, the method comprising providing a non-linear immobilized pH gradient (IPG) strips of acrylamide polymer 3 mm x 180 mm.

SEQUENCE ELECTION REQUIREMENT APPLICABLE TO GROUPS I, II, III, AND IV

In addition, Groups I, II, III, and IV detailed above reads on patentably distinct protein sequences as set for in claim 29 (Group I), claim 34 (Group II), and claims 46-49 (Group IV). Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to protein sequences, the Applicant must elect a single disclosed protein sequence, a subset of a single disclosed protein sequence, or an unspecified protein sequence. Applicant reminded than an election of a subset of a single disclosed protein sequence must be a specifically disclosed subset to avoid a potential NEW MATTER rejection. Examination will be restricted to only the elected sequence. It is additionally noted that this sequence election is part of the invention election requirement and not a specie election requirement.

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D. can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Ardin H. Marschel 1/23/05
ARDIN H. MARSCHEL
PRIMARY EXAMINER